

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Food and Drug Administration

Memorandum

Date: May 14, 2010

From: Chemical Hazard Assessment Team, HFS-301

Subject: Oil Spill Chemical Dispersants

To: Peter Koufopoulos, Supervisory CSO

OCD/OFS/DSS HFR-NE2520

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The recent drilling rig explosion off the coast of Louisiana resulted in a major oil spill. To minimize the environmental impact of the oil spill, chemical dispersants, such as COREXIT® EC9527A and COREXIT® 9500 have been applied as remediation products. As part of FDA's effort to monitor the development of this crisis and its potential impact on the safety of seafood harvested from the Gulf of Mexico, this is an assessment of the potential toxic human health impact of the chemical dispersants as per their potential to adversely impact seafood.

Dispersants are specially designed oil spill products that are composed of detergent-like surfactants in low toxicity solvents that reduce interfacial tension between oil and water in order to enhance the natural process of dispersion by generating larger numbers of small droplets of oil that are entrained into the water column by wave energy (NRC, 2005).

Though early dispersants contained agents highly toxic to marine life, manufacturers have refined formulations of more recent generations of dispersants to dramatically reduce toxicity. Current dispersants contain solvents composed of nonaromatic hydrocarbons or water-miscible concentrates (alcohols or glycols) as well as less toxic surfactants (U.S. EPA, 1996; Fiocco and Lewis, 1999; NRC (National Research Council), 1989). Moreover, in its 2005 report the NRC stated that there has been little evidence that contradicts the conclusion that the potential acute lethal toxicity of chemically dispersed oil is primarily associated with the dispersed oil and dissolved oil constituents following dispersion and not with the current generation of dispersants.

A report by Lunel et al., 1997 states that monitoring following the Sea Empress oil spill incident in the United Kingdom demonstrated that the use of dispersants resulted in a net environmental benefit and that the potential toxic effects as the result of the dispersant application are due to the enhanced volumes of dispersed oil and not from the dispersant itself. Furthermore, a study by Richard et al., 1999 suggested that addition of dispersants can increase the rate of biodegradation under natural conditions by promoting the growth of indigenous hydrocarbon degrading bacteria, as well as increasing the surface area of oil available for microbial colonization.

The Material Safety Data Sheet (MSDS), provided by the manufacturer states that no toxicity tests have been conducted on either EC9527A or COREXIT® 9500, and that the component substances of 9500 have a potential to bioaccumulate, while the ones in 9527A have a low potential to bioaccumulate. No supporting information (e.g., references) regarding bioaccumulation was provided in the MSDS. To verify this and to identify data and information relevant to human exposure to the chemical dispersants, we conducted literature searches that yielded no information on the bioaccumulation potential of the component substances. However, we did find the following information regarding the component substances of the dispersants:

- Propylene glycol, a component substance in both of the dispersants, is generally recognized as safe (GRAS) by the U.S. Food and Drug Administration (FDA) in 21 CFR § 184.1666, for use as a direct food additive under the conditions prescribed.
- An Agency for toxic substances and Disease Registry (ATSDR) toxicological profile report indicates that 2-butoxyethanol, a component of EC9527A, has insignificant potential for bioaccumulation (ATSDR, 1998).
- In addition, organic sulfonic acid salt whose chemical identity is considered proprietary is reported to be readily biodegradable, non-bioaccumulative, and moderately toxic to fresh water fish and invertebrates in the manufacturer's product stewardship summary report (not provided).

A few studies have reported that chemical dispersants may enhance the bioaccumulation potential of dispersed oil (Mielbrecht et. al, 2005; Wolfe et. al, 2000). However, these studies were conducted in laboratory wave tanks which may not have relevance to the actual situation in the Gulf of Mexico oil spill. In addition, a study by Yakata et. al, 2006 indicated that dispersants had no influence on the bioaccumulation potential of seven organic compounds, some of which are found in oil, with different lipophilicities and structures, and concluded that dispersants had no effect on the bioaccumulation of these compounds in fish.

In conclusion, the available information indicates that dispersants have little or no effect on the bioaccumulation potential of oil contaminants, nor do they themselves accumulate in seafood.

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HFS-300 (Beru) HFS-300 (Kraemer) HFS-325 (William) HFS-400 (Dickey)

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